

The FDA has begun to talk about the issue: "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff" issued on August 13, 2013, includes a request for comments and recommendations on the QoS (section 3b.): [7]

3b. Wireless Quality of Service

Wireless Quality of Service (QoS) refers to the necessary level of service and performance needed for the wireless functions of the medical device. While the QoS of cellular telephone networks might be acceptable for voice communication, it might not be sufficient for certain medical functions. Connections lost without warning, failure to establish connections, or degradation of service can have serious consequences, especially when the medical device relies heavily on the wireless connection. Such situations can compromise the wireless transmission of high-priority medical device alarms, time-sensitive continuous physiological waveform data, and real-time control of therapeutic medical devices (such as wireless footswitches).

If a wireless medical device becomes part of a network, wireless QoS should be carefully considered in conjunction with the intended use of the wireless medical device. The following factors should be assessed when developing QoS standards: acceptable latency, acceptable level of probability for loss of information within the network, accessibility, and signal priorities of the network.

When the network is chosen or designated, FDA recommends use of a risk management approach to deployment, security, and maintenance of the network's QoS. Depending on the intended use of the device, additional failure modes may need to be considered. Once failure modes and associated risks are identified, we recommend a justification of acceptable risk, or testing or other measures to demonstrate appropriate risk mitigation.

6 Recommendations for Solutions – mHealth over Reliable Broadband Networks

The discussion so far has centered on the infrastructure that underlies smartphone technology, a key factor in establishing universal mHealth and telemedicine. Another essential issue that must be addressed is regulations, specifically regulation of medical devices/smartphone applications and technologies.

In Canada, a comprehensive approach to interoperability, ubiquitous scalability, data management and ownership, remote monitoring, dependability assessment and end-to-end QoS standardization, has been proposed to Industry Canada (equivalent to the FCC in the U.S.). **This wide-ranging solution can be achieved by including mHealth in the dedicated spectrum that has already been allocated to public safety.**

Leading the advocacy of this solution is the Canadian Advances Technology Association Campaign (CATAAlliance). The CATAAlliance's solution, "mHealth Real Time," forms an integral part of the industry's Innovation Nation

program, a program, under the tutelage of Canada's leading entrepreneur, Sir Terence Matthews, which lays out what Canada must do as a nation to achieve digital leadership for the 21st Century.

According to CATAAlliance's CEO, John Reid, "Recent emergencies in public health and increased reliance on mHealth have demonstrated the urgency of getting the right information securely into the hands of those who need it the most, in real time, and across jurisdictional boundaries...Enhancing quality, improving convenience, extending reach and reducing costs of healthcare are the potential benefits of mHealth, should the underlying mobile infrastructure be designed to provide ubiquitous broadband 'medical grade' performance...Local governments, public safety and healthcare agencies across the country are evaluating the benefits of broadband wireless mobile networks for remote access to information, both mission critical and routine, to improve real-time awareness for better decision making and to enhance collaboration and information sharing."

The Canadian Federal Government has recognized the situation and has allocated mobile broadband (20 MHz under consideration) dedicated spectrum in the 700 MHz band to be shared by all public safety agencies operating in Canada under municipal, provincial and federal jurisdictions. This band is the same band that has been allocated by the FCC to its PRTSS communities. The spectrum must be cleared within 100 kilometers of the border, which includes the majority of the Canadian population.

EMS (Emergency Medical Services) is included in the definition of "Public Safety" and will have access to the dedicated spectrum. However, mHealth and Healthcare in general and Telemedicine in particular are not included, unless Industry Canada recognizes the needs of mHealth in its review.

Industry Canada is currently evaluating and considering, in a public consultation process (SMSE-007-12), [1, 2] this key issue which embodies unprecedented opportunities for Canada's Digital Leadership in the 21st Century.

The question is: "Who, besides Police, Fire, and EMS, should have access to the secure LTE dedicated broadband mobile network, once it is deployed across the country?"

The digital leadership answer is: m-Health/Healthcare and other Public Real Time Social Services.

The opportunities for Canada and the healthcare industry worldwide arise from the fact that the same 20 MHz spectrum that the FCC has allocated exclusively to Public Safety in the U.S. has also been recommended for allocation in Canada. But Canada, with 1/10 the population of the United States, has just 1/10 of the traffic demand. So, if it chooses to include healthcare in this dedicated spectrum, Canada can easily accommodate mHealth within its own borders. In contrast, Homeland Security and first respondents in the U.S. understandably argue they need the full 20 MHz just for emergency responses.

The efficiencies and cost reductions that will be generated by ubiquitous mHealth use would greatly help fund the building and the ongoing operation of the countrywide (province by province) deployment of public safety/medical grade broadband mobile networks. As we have discussed, these savings and the

widespread adoption of mHealth by the medical profession will occur only if the underlying wireless/mobile infrastructure is fully trustworthy end-to-end, via “medical grade” dedicated mHealth networks.

In Canada such efficiency improvements may represent annual savings of 15 billion dollars.

The R.O.I (Return on Investments) associated with healthcare participation in the dedicated Public Safety spectrum would justify the building of ubiquitous networks for all mobile Public Real-Time Social Services’ needs. Emergency and real-time access to services would be secure and reliable.

Without Provincial Healthcare participation, the municipal Police, Fire, and EMS authorities will not be able to fund and justify the operating cost from operational savings.

Spectrum availability by itself will not produce the full benefits to society; the Return on Investment will come from the construction of a dedicated, secure, broadband mobile infrastructure, available *all-the-time, and everywhere*, encompassing all Public Real-Time Social Services, including:

- Fire (Municipal and Provincial)
- Police (Municipal, Provincial, Territorial, and Federal)
- EMS (Municipal)
- Healthcare (Provincial and Federal)
- Utilities (Provincial and Federal)
- Other governmental Real-Time Social Services
- Jointly named: Government provided; Public Real-Time Social Services (PRTSS)

Governments need to develop strategic e-Health frameworks in order to provide access to dedicated mobile spectrum of which mHealth is an integral component.

Such frameworks will enable them to provide mHealth implementers with more guidance when deploying projects, to ensure alignment with their governments’ e-Health information systems and other relevant policies to leverage technology for public good. Government involvement should include national health priorities, enterprise architecture for interoperability and data standards, and commonly used metrics for assessing the impact of m-Health.

CATAAlliance’s CEO John Reid notes that, “If Canada is to become a competitive Innovation Nation, we’ve got to excel in key sectors such as healthcare where given the right conditions we can create new flagship enterprises and hundreds of SME’s (Small Medium Enterprises) to supply domestic and global healthcare needs.”

Including mHealth in public safety networks is once-in-a-lifetime opportunity for Canada to establish worldwide leadership in “medical grade” mobile networks. This inclusion would facilitate the deployment of such networks throughout the world for years to come.

Now, let's go back to the train disaster scenario. Imagine it all happening in the future with the benefit of mHealth; i.e., over a PRTSS dedicated broadband mobile LTE network.

The Command and Control Incident (CCI) field H.Q. is quickly established on the scene upon the arrival of the first responders - police, fire and ambulance (EMS). It establishes priorities by assigning responders to various rescue operations, based on the urgency of the situation in each case (all responders of all three agencies come under the control of the CCI). All communication is done over the data/video/voice network.

Full interoperability between the three first responder groups allows seamless coordination on the scene and with their respective home bases in a pre-rehearsed precise manner. Information from building layouts, such as water, gas and electricity distributions for the entire two affected city blocks, are downloaded instantly for viewing by all responders via their mobile devices. Simultaneous video, data and voice communications on split (real-time) screens make operations' support extremely efficient.

7 Achieving Quality of Service

Now let's zoom into the unfortunate, injured, middle aged man. Earlier, we left him lying motionless without any signs of bleeding, and with a very weak pulse and shallow breathing. His fate was sealed by poor communication quality among the dispatcher, the hospital, and the paramedic leading to a fatal overdose.

In a mHealth future, the paramedic in charge immediately presses the patient's thumb (to transmit his finger print) onto the glass front of his mobile device and instantaneously receives the man's picture, ID and a request for an access code to his medical EHR (Electronic Health Records).

The paramedic enters his authorization code and gets the patients' health records which indicate that a serious sensitivity to Epinephrine (the drug that killed him in our early scenario). The paramedic clicks on the "sensitivity" field on the screen and four alternative drugs are displayed, with proper application instructions. Needless to say, the patient would still be alive, under this mHealth operational scenario.

8 The Growing Demand for Reliable mHealth Transactions

In addition to ameliorating crisis management, as is widely discussed in the literature and in this book, reliable mHealth will have wide-reaching benefits in managing the health of aging populations worldwide. Accurate and reliable patient monitoring, facilitated by mHealth applications, will be key to the burgeoning "home care" transformation of the healthcare industry, as the percentage of the aging population continues to grow. Reliable, real-time monitoring over commercial, unsecure wireless networks, as is the case today, will simply not be

possible because of the structural limitations of the commercial infrastructure we have discussed.

9 Conclusion

In this chapter we have discussed the critical need for the medical profession to operate with sufficient confidence in the reliability, accuracy and security of the underlying wireless infrastructures on which mHealth applications and transactions are being conducted.

We also discussed the fundamental point, that unless such confidence can be sustained the potential benefits of mHealth will remain unrealized.

“There is a fear that oversight in the development of mobile medical apps will present risks to patients if the networks fail to work effectively.” [17]

The recommended solution, currently being contemplated in Canada, is the integration of mHealth and healthcare in general, with EMS (Emergency medical Service) and other Public Real-Time Social Services (PRTSS), user group. The PRTSS user group will be licensed by the government as a dedicated RF (Radio Frequency) spectrum to facilitate the design, deployment and operation of an independent dedicated broadband wide area mobile infrastructure.

This solution will enable the medical profession to benefit from mHealth under similar reliability and security conditions, with due process priorities, as is being contemplated for “first responders” (police, fire and EMS) worldwide.

As this (Canadian) solution unfolds, further understanding and research of various alternatives should be undertaken, particularly if funding limitation were slow to the speed with which these networks are implemented and made available to the medical communities.

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6. Communication Issues in Pervasive Healthcare Systems and Applications – Chapter 10 – By Demosthenes Vouyioukas and Ilias Maglogiannis (<http://www.icsd.aegean.gr/dvouyiou/dmdocuments/pubs/BOOK%20CHAPTERS/IGI/978-1-61520-765-7.ch010.pdf>)
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Questions

- Q1. How will medical staff access the PRTSS networks, and would they need a different smartphone or tablet?
- Q2. In major emergencies, how will the PRTSS network be configured to allow various agencies (Police, Fire, EMS healthcare, etc...) to simultaneously access and convey large amount of information?
- Q3. How will PRTSS networks be funded?
- Q4. Will governments be willing to allocate cellular compatible "mobile spectrum" for mHealth rather than auction it to the higher bidder?
- Q5. Why would public wireless mobile carriers not accommodate a priority secure and reliable service for PRTSS use?